

Remarks/Arguments:

Original claims 23-25 have been cancelled. Claims 13, 29, and 30 have been amended in relatively minor respects. No new matter has been introduced. Entry of this preliminary amendment is requested.

During prosecution of the parent application, Number 09/991,123, the Examiner rejected independent claims 1 and 13 under 35 U.S.C. § 103(a) as obvious over a combination of several references, including U.S. Patent No. 5,498,709 ("Navia et al."). The Examiner conceded that Navia et al. do "not disclose adjusting the pH to the specified range." Final Office Action dated December 20, 2002 at page 3. The Examiner advanced, however, the following position:

But Navia discloses that the crystallization is done in an aqueous solution (same as the instant claims). The pH of water is 7, which is well know [sic, a well known] fact in the art and to one of ordinary skill. Since water is the crystallization solvent in Navia's process, it can be understood by one of ordinary skill in the art that the pH during the crystallization process is 7 or close to 7, which is well within the range specified. Hence [the] question of adjusting the pH doesn't arise unless it is obvious that the pH in Navia's process is outside the specified range.

Final Office Action dated December 20, 2002 at page 3.

As noted by the applicants on page 2, lines 20-27, of the instant application, rather than remaining neutral at a pH of 7.0, an aqueous solution comprising sucralose typically becomes highly acidic during processes of sucralose crystallization. Once sucralose is added to water, at least without a buffer (and it is not seen where Navia et al. disclose a buffer), the pH of the solution immediately drops to well below 5.5 (i.e., the solution becomes highly acidic). This drop in pH occurs because minute amounts of sucralose break down and release hydrochloric acid. See Specification at page 2, lines 25-27. Thus, if the hypothetical person of ordinary skill in the art would understand, as the Examiner proposes, "that the pH during the crystallization process is 7 or close to 7," then that artisan would be mistaken.

Such acidity is one of the problems solved by the applicants' claimed invention. Nowhere is it seen where Navia et al. teach or suggest that the pH of a solution from which sucralose is crystallized is within the range recited by claims 1 and 13. Nor is it seen where Navia et al. teach or suggest any process including a step of controlling or adjusting the pH of a solution to a level within any range, let alone the pH range recited within claims 1 and 13.

An analysis under Section 103 is controlled by *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and requires, as the first of its four analytical steps, determining the scope and content of the prior art. The scope of the prior art is determined, in part, by the problem addressed by the applicants, not by the claimed invention. Put another way, it is not determined by the solution to the problem which the applicants have solved. For the invention under consideration, one problem addressed by the applicants is stated in the specification on page 2, lines 20-27: that is one of an acidic sucralose containing solution.

On the other hand, the problem addressed by Navia et al. was the direction of chlorine atoms to only the desired positions in the molecular structure of sucrose, difficult because the hydroxyls that are replaced by the chlorine are of differing reactivity, during synthesis of sucralose from sucrose. See Navia et al. patent at column 1, lines 35-37. Thus, it does not appear that Navia et al. address the same problem as the claimed invention. Under comparable circumstances, the CCPA stated:

[A] person having the references before him who was not cognizant of appellant's disclosure would not be informed that the problems solved by the appellant ever existed. Therefore, can it be said that these references which never recognized appellant's problem would have suggested its solution? We think not, and therefore feel that the references were improperly combined since there is no suggestion in either of the references that they can be combined to produce appellant's result.

In re Shaffer, 108 USPQ 326, 329 (CCPA 1956).

The issue raised under Section 103 is whether "the subject matter as a whole" would have been nonobvious. Two aspects of this point are important. First, it is "the subject matter as a whole" which is the focus, not merely the differences between the subject matter and the prior art. Thus, the issue is whether the subject matter as a whole, not the differences, would have been nonobvious. *Carl Schenck, A.G. v. Nortron Corp.*, 218 USPQ 698, 700 (Fed. Cir. 1983).

As a second aspect, "the subject matter as a whole" includes the insights of the applicants which motivated the invention. *Id.* Put another way, "the subject matter as a whole" includes the conception of the invention as well as its reduction to practice. *In re Spinnoble*, 160 USPQ 237, 243 (CCPA 1969) ("It should not be necessary for this court to point out that a patentable invention may lie in the discovery of the source of a problem This is

part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103."). In fact, in Sponnoble, the Court upheld the patentability of claims partially because the applicant had discovered the unknown path of a known, problematic transmission of moisture.

The point must be kept in mind at all times, because the decisionmaker must not imbue one of ordinary skill in the art with knowledge of the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 312-313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). References cannot be taken for more than they would have suggested to one of ordinary skill in the art. The decisionmaker cannot engage in conjecture as to what an artisan might have noted about the prior art.

A finding that the present invention is obvious over the cited references is fatally flawed because it ignores both the insight, or conception, of the invention and the functions of the invention. The finding is flawed for ignoring "the subject matter as a whole" as required under 35 U.S.C. § 103. Thus, the applicants do not agree with the stated position that the disclosure of Navia et al., individually or when combined with the other documents cited during prosecution of the parent application, supports a prima facie case of obviousness for the invention as recited in claims 1 and 13. Although the Examiner may view the claimed invention as being simple, the Examiner is reminded that "the simplicity of new inventions is often the very thing that is not obvious before they are made. . . . The fact that the invention seems simple after it is made is not determinative of the question of obviousness." *In re Van Wanderhorn, Worthley, and Conolli*, 154 USPQ 20, 24 (CCPA 1967).

In an Advisory Action dated April 4, 2003, during prosecution of the parent application, the Examiner stated:


Applicants argue that the [sic] Navia et al do not teach or suggest the process of independent claims 1 and 13 comprising the step of adjusting or controlling the pH of the solution within the range from about 5.5 to about 8.5. The claims are [sic, are] not limited to any specific pH controlling methodological procedure or step.

The applicants fail to understand the relevance of the second sentence of the highlighted statement. Independent claims 1 and 13 are limited to, among other things, the process step of "controlling" (claim 1) or "adjusting" (claim 13) the pH of the sucralose containing solution.

It is not seen where the cited documents teach or suggest this step, either alone or in combination, and, therefore, no more specific recitation of the "controlling" or "adjusting" step is necessary to impart patentability to the pending claims. If the Examiner maintains otherwise, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Consideration of this preliminary amendment and favorable action are earnestly solicited.

Respectfully submitted,


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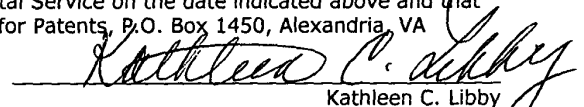
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